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SHUMAKER & SIEFFERT, P. A. 8425 SEASONS PARKWAY SUITE 105 ST. PAUL, MN 55125			WILLIAMS, KENNETH C	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,121

Applicant(s)

BRISCOE ET AL.

Examiner

Kenneth C. Williams

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/12/04, 5/24/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: IDS 7/1/04,9/30/04,11/19/04,2/22/05,6/16/05.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5, 9, 12, 14-17, 21, 26-31, 33-34, 37-39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Nenov (U.S. Patent No. 6416480).
 - a. In regards to Claim 1, Nenov discloses a method comprising “receiving data concerning a patient” (See Figure 2, elements 24 and 28; also see column 8, line 62-column 9, line 4) and “selecting a brain injury protocol as a function of the data” (See Nenov column 1, lines 13-20).
 - b. In regards to Claim 2, Nenov discloses a method comprising “receiving the data from an operator” (See column 9, lines 60-64).
 - c. In regards to Claim 3, Nenov discloses a method comprising “receiving the data from a monitoring device” (See Figure 3B, elements 24, 28 and 42; also see column 10, lines 30-32).
 - d. In regards to Claim 5, Nenov discloses a method comprising “the data comprise at least one of a physical condition of the patient, a mental condition of the patient and a complaint from the patient” (See column 3, lines 53-56).
 - e. In regards to Claim 9, Nenov discloses a method comprising “presenting an operator with a task to be performed pursuant to the brain injury protocol; and

receiving an acknowledgement from the operator that the task has been performed” (See Figure 2, elements 22, 24, 26,28). In order for the operator of the Nenov invention to follow its brain injury protocol, the operator first must perform the task of attaching the electrodes to the patient. Further, the Nenov invention receives an acknowledgement from the operator by being able to monitor the physiological data of the patient.

f. In regards to Claim 12, Nenov discloses a method comprising “presenting a checklist to an operator pursuant to the brain injury protocol, the checklist requesting entry of additional data concerning the patient; and receiving the additional data from the operator” (See Figures 4a and 4b; see also column 15, lines 24-39). The operator in the Nenov reference is interpreted to be the computer, element 18 of Figure 2.

g. In regards to Claims 14 and 17, Nenov discloses a method comprising “further comprising determining a presumptive diagnosis as a function of the data” (See Figures 5A-5D; also see column 1, lines 13-20 and column 17, lines 9-50).

h. In regards to Claim 15, Nenov discloses a method comprising “presenting a checklist to an operator, the checklist requesting entry of data concerning a neurological condition of a patient” (See Figures 4a and 4b; see also column 15, lines 24-39), “receiving the data from the operator” (See column 9, lines 60-64), “receiving additional data concerning the patient from a monitoring device” (See Figure 3B, elements 24, 28 and 42; also see column 10, lines 30-32), and

“selecting a brain injury protocol as a function of the data” (See column 1, lines 13-20).

i. In regards to Claim 16, Nenov discloses a method comprising “the checklist comprises at least one of a Cincinnati Prehospital Stroke Scale, a Los Angeles Prehospital Stroke Screen, a Glasgow Coma Scale and a Hunt and Hess Scale for Subarachnoid Hemorrhage” (See column 1, lines 13-20).

j. In regards to Claim 21, Nenov discloses a system comprising “a monitoring device to monitor a medical condition of a patient and to generate data concerning the patient” (See Figure 2; also see column 10, line 66-column 11, line 5) and “a processor to receive the data from the monitoring device and to select a brain injury protocol as a function of the data” (See Figure 2, element 18; also see column 9, lines 5-21). Element 18 is a computer which contains a processor.

k. In regards to Claim 26, Nenov discloses a system comprising “an input device to receive additional data concerning the patient from an operator” (See Figure 2, see also column 8, line 62 – column 9, line 4).

l. In regards to Claim 27, Nenov discloses a system comprising “the input device comprises at least one of a button, a keyboard, a touch screen, a voice recognition module and a pointing tool” (See Figure 2, element 14)

m. In regards to Claim 28, Nenov discloses a system comprising “an output device to present brain information pursuant to the brain injury protocol” (See Figure 2, element 16; see also column 8, lines 65-67).

- n. In regards to Claim 29, Nenov discloses a system comprising “the output device comprises at least one of a touch screen, a display screen, an audible sound generator, a voice synthesizer, a printer and an indicator light” (See Figure 2, element 16; see also column 8, lines 65-67).
- o. In regards to Claim 30, Nenov discloses a system comprising “memory to store at least one of a brain injury protocol and a datum concerning the patient” (See column 6, lines 15-18).
- p. In regards to Claim 31, Nenov discloses a system comprising “a communication module to transmit data stored in the memory to a remote unit” (See Figure 3B; also see column 9, lines 22-33).
- q. In regards to Claim 33, Nenov discloses a computer-readable medium comprising “instructions for causing a programmable processor to: receive data concerning a patient; and select a brain injury protocol as a function of the data” (See column 22, line 60 – column 23, line 11).
- r. In regards to Claim 34, Nenov discloses a computer-readable medium comprising “the instructions causing the processor to receiving the data from at least one of an operator and a monitoring device” (See column 22, line 60 – column 23, line 11).
- s. In regards to Claims 37 and 41, Nenov discloses a computer-readable medium comprising “instructions causing the processor to determine a presumptive diagnosis as a function of the data” (See column 17, lines 9-50 and column 22, line 60 – column 23, line 11).

t. In regards to Claim 38, Nenov discloses a computer-readable medium comprising "instructions for causing a programmable processor to: present a checklist to an operator, the checklist requesting entry of data concerning a neurological condition of a patient; receive the data from the operator; receive additional data concerning the patient from a monitoring device; and select a brain injury protocol as a function of the data" (See column 15, lines 24-39 and column 22, line 60 – column 23, line 11).

u. In regards to Claim 39, Nenov discloses a computer-readable medium comprising "the checklist comprises at least one of a Cincinnati Prehospital Stroke Scale, a Los Angeles Prehospital Strike Screen, a Glasgow Coma Scale and a Hunt and Hess Scale for Subarachnoid Hemorrhage" (See column 22, line 60 – column 23, line 11).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 4, 18 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Williams et al. (U.S. Patent No. 6406427).

a. In regards to Claim 4, Nenov discloses a method using EMG and EOG electrodes (See Claim 1 Rejection). Nenov does not disclose, "the data from the monitoring device comprises at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a respiration, a blood velocity, an EEG, an ECG, and a body temperature". Attention is directed to the Williams et al. reference, which in a similar field of endeavor discloses the desirability of receiving EEG, ECG, and other data from a monitoring device (See Williams et al. column 2, lines 14-49). ~~Therefore~~ ^{Therefore,} to aid in the treatment of brain injuries, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Nenov to receive data from at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a respiration, a blood velocity, an EEG, an ECG, and a body temperature as taught by Williams et al. in order to more accurately assess the severity of a brain injury.

b. In regards to Claim 18, Nenov discloses a method using EMG and EOG electrodes (See Claim 15 Rejection). Nenov does not disclose, "the data from the monitoring device comprises at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a

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respiration, a blood velocity, an EEG, an ECG, and a body temperature”.

Attention is directed to the Williams et al. reference, which in a similar field of endeavor discloses the desirability of receiving EEG, ECG, and other data from a monitoring device (See Williams et al. column 2, lines 14-49). ~~Therefore~~ to aid in the treatment of brain injuries, ^{therefore,} it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Nenov to receive data from at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a respiration, a blood velocity, an EEG, an ECG, and a body temperature as taught by Williams et al. in order to more accurately assess the severity of a brain injury.

c. In regards to Claim 32, Nenov discloses a system using EMG and EOG electrodes (See Claim 21 Rejection). Nenov does not disclose “the monitoring device comprises at least one of a heart rate monitor, a pulse monitor, a blood pressure monitor, a carbon dioxide concentration sensor, a blood oxygen concentration sensor, a blood velocity sensor, an EEG monitor, an ECG monitor, and a body temperature sensor”. Attention is directed to the Williams et al. reference, which in a similar field of endeavor discloses the desirability of receiving EEG, ECG, and other data from a monitoring device (See Williams et al. column 2, lines 14-49). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Nenov to receive data from at least one of a heart rate, a pulse, a blood pressure, a carbon dioxide concentration, a blood oxygen concentration, a respiration, a blood velocity, an

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EEG, an ECG, and a body temperature as taught by Williams et al. in order to more accurately assess the severity of a brain injury.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Bridger et al. (U.S. Patent 6887199).

In regards to Claim 6, Nenov disclose a method (See Claim 1 Rejection). Nenov does not disclose, "the brain injury protocol comprises one of an ischemic stroke and a hemorrhagic stroke protocol". Attention is directed to the Bridger et al. reference, which in a similar field of endeavor discloses a brain assessment tool used to detect conditions such as head trauma, stroke, and hemorrhage (Bridger et al. column 3, lines 27-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a brain injury protocol for an ischemic stroke and/or a hemorrhagic stroke to the device of Nenov because such protocols would reduce the delay time in making a diagnosis of the type of brain injury, thus increasing the amount of time for therapeutic intervention.

7. Claim 7, 8,13, 19, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Clifton (U.S. Patent No. 5486204).

a. In regards to Claim 7, Nenov discloses a method (See Claim 1 Rejection). Nenov does not disclose, "further comprising controlling a therapy device according to the brain injury protocol". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses controlling a therapy device according to a brain injury protocol (See Clifton column 3, lines 17-23). It

would have been obvious to one of ordinary skill in the art at the time of the invention to have the device of Nenov control a therapy device according to the brain injury protocol because the protocol would encompass procedures for examining, evaluating and treating patients with actual or suspected brain injury, which would involve using a type of therapeutic device.

b. In regards to Claim 8, Nenov discloses a method (See Claim 1 Rejection). Nenov does not disclose, "the therapy device comprises one of a cooling device and a drug delivery device". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses the use of a cooling blanket, a muscle relaxant and a sedative to treat brain trauma (See Clifton column 3, lines 24-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to include controlling a cooling therapy device or drug delivery device in the brain injury protocol of Nenov because creating a hypothermic environment for the patient is a method of treatment for brain injuries, which involves the use of cooling and drug delivery devices as taught by Clifton.

c. In regards to Claim 13, Nenov discloses a method (See Claim 12 Rejection). Nenov does not disclose, "further comprising controlling a therapy device as a function of the additional data". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses controlling a therapy device according to a brain injury protocol (See Clifton column 3, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to control a therapy device according to the brain injury protocol

because the protocol would encompass procedures for examining, evaluating and treating patients with actual or suspected brain injury, which would involve using a type of therapeutic device.

d. In regards to Claim 19, Nenov discloses a method (See Claim 15 Rejection). Nenov does not disclose, "further comprising controlling a therapy device according to the brain injury protocol". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses controlling a therapy device according to a brain injury protocol (See Clifton column 3, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to control a therapy device according to the brain injury protocol because the protocol would encompass procedures for examining, evaluating and treating patients with actual or suspected brain injury, which would involve using a type of therapeutic device.

e. In regards to Claim 22, Nenov discloses a system (See Claim 21 Rejection). Nenov does not disclose, "further comprising a therapy device to provide brain injury protocol as a function of the data". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses a therapy device to provide brain injury therapy (See Clifton column 3, lines 24-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide to the device of Nenov in light of the teaching of Clifton a therapy device to treat a brain injury because a therapy device is a tool used to improve the condition of a patient with a brain injury.

- f. In regards to Claim 25, Nenov discloses a system (See Claim 22 Rejection). Nenov does not disclose, "the therapy device comprises one of a cooling device and a drug delivery device". Attention is directed to the Clifton reference, which in a similar field of endeavor discloses the use of a cooling blanket, a muscle relaxant and a sedative to treat brain trauma (See Clifton column 3, lines 24-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a cooling therapy device or drug delivery device in Nenov because creating a hypothermic environment for the patient is a method of treatment for brain injuries as taught by Clifton.
8. Claims 10, 11, 20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Zak et al (U.S. Patent Application Publication No. US2002/0004729).

a. In regards to Claim 10, Nenov discloses a method (See Claim 1 Rejection). Nenov does not disclose "storing in an event log at least one of an action taken in the course of attending to the patient, a reception of the data from a monitoring device and a therapy delivered by a therapy device". Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses storing patient treatment information in an event log (See Figure 9, element 400; also see Paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of the invention to store information in an event log in order to provide a medical treatment history that could be used to aid in the further treatment of the patient.

b. In regards to Claim 11, Nenov discloses a method (See Claim 10 Rejection). Nenov does not disclose, “transmitting the event log to a remote unit” Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses transmitting patient data remotely (See Figure 1; also see Paragraph 55). It would have been obvious to one of ordinary skill in the art at the time of the invention to transmit the event log to a remote unit because providing information to a treatment facility in advance of the patient’s arrival reduces the delay in treating the patient.

c. In regards to Claim 20, Nenov discloses a method (See Claim 15 Rejection). Nenov does not disclose “further comprising storing in an event log at least one of an action taken in the course of attending to the patient, a reception of the data from a monitoring device and a therapy delivered by a therapy device”. Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses transmitting patient data remotely (See Figure 9, element 400; also see Paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of the invention to store information in an event log in order to provide a medical treatment history that could be used to aid in the further treatment of the patient.

d. In regards to Claim 36, Nenov discloses a computer-readable medium (See Claim 33 Rejection). Nenov does not disclose “instructions causing the processor to store in an event log at least one of an action taken in the course of attending to the patient, a reception of the data from a monitoring device and a

therapy delivered by a therapy device”. Attention is directed to the Zak et al. reference, which in a similar field of endeavor discloses associating a procedure performed on a patient with a time stamp (See Paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a computer readable medium with instructions to compile information in an event log because providing a medical treatment history could be used to aid in the further treatment of the patient.

9. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Clifton (U.S. Patent No. 5486204) as applied to claim 22 above, and further in view of Klatz et al. (U.S. Patent No. 6277143).

a. In regards to Claim 23, Nenov in view of Clifton discloses a system (See Claim 22 Rejection). Nenov in view of Clifton does not disclose, “the processor is configured to control the therapy device as a function of the data”. Attention is directed to the Klatz et al. reference, which in a similar field of endeavor discloses a therapy device controlled by a microprocessor (See Klatz et al. column 11, line 57 – column 12, line 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a processor configured to control a therapy device as a function of the data because the processor would enhance the control of the therapy device through automating its control.

b. In regards to Claim 24, Nenov in view of Clifton discloses a system (See Claim 22 Rejection). Nenov in view of Clifton does not disclose, “the processor is

configured to control the therapy device as a function of the brain injury protocol”.

Attention is directed to the Klatz et al. reference, which in a similar field of endeavor discloses using a microprocessor to control a brain cooling apparatus (See Klatz et al. column 12, lines 6-9). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a processor configured to control a therapy device as a function of the brain injury protocol because the processor would enhance the control of the therapy device through automating its control.

10. Claims 35 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nenov (U.S. Patent No. 6416480) in view of Klatz et al. (U.S. Patent No. 6277143).

In regards to Claims 35 and 40, Nenov discloses a computer-readable medium (See Claim 33 Rejection and Claim 38 Rejection). Nenov does not disclose “instructions causing the processor to control a therapy device according to the brain injury protocol”. Attention is directed to the Klatz et al. reference, which in a similar field of endeavor discloses using a microprocessor to control a brain cooling apparatus (See Klatz et al. column 12, lines 6-9). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a computer-readable medium with instructions to control a therapy device according to the brain injury protocol because the medium provides an enhancement in the control of the therapy device by automating its controls.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth C. Williams whose telephone number is (571) 272-8161. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCW



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700